

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

AEGIS SCIENCES CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	No.
)	
MILLENNIUM LABORATORIES, INC.,)	JURY DEMANDED
)	
Defendant.)	

COMPLAINT

Plaintiff, Aegis Sciences Corporation (“Aegis”), for its Complaint against Defendant Millennium Laboratories, Inc. (“Millennium”) for Monetary Damages, Injunctive Relief, and Declaratory Relief states as follows:

INTRODUCTION

Aegis brings this action for injunctive relief, disgorgement of ill-gotten gains and damages caused by Millennium’s numerous, ongoing, and constantly evolving schemes to defraud federal and state health care programs (such as Medicare and Medicaid) and private payors and insurers. Millennium’s panoply of schemes include illegal kickbacks, fee sharing arrangements, and fraudulent, unnecessary and duplicative testing and billing practices, all of which are intended to induce business relationships with Millennium in exchange for its promise to “maximize profits” for its physician customers, but are without regard to the medical necessity or value of such testing and billing schemes. Millennium’s illegal acts are done in unfair competition with Aegis and in violation of its rights.

THE PARTIES

1. Plaintiff Aegis Sciences Corporation is a Tennessee corporation with its principal place of business at 515 Great Circle Road, Nashville, Tennessee 37228.

2. Aegis is an independent drug testing laboratory, certified by the United States Department of Health and Human Services Substance Abuse and Mental Health Services Administration (DHHS/SAMHSA) and by the American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB), Clinical Laboratory Improvement Amendments (CLIA), and the regulatory licensing bodies for the states of Tennessee, New York, Florida, Maryland and Pennsylvania.

3. Aegis provides sports and workplace drug testing, as well as other types of toxicology services to organizations throughout the United States and the world. In addition to such services, Aegis also provides drug testing services for pain management physicians. These compliance testing services involve analysis of urine and/or oral fluid for the presence of illegal or prescription drugs, and drug metabolites, at the Aegis laboratories in Nashville, Tennessee.

4. Defendant Millennium is a California corporation and has its principal place of business in San Diego, California. Millennium has been registered to do business, and does conduct business, within the State of Tennessee. Millennium is a provider of services to beneficiaries of federally funded health programs.

5. Millennium actively competes with Aegis in the market for pain management drug testing services in Tennessee and elsewhere for pain management physicians.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1331 because one or more of Aegis's claims asserted against Millennium arise under federal law.

7. This Court also has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

8. This Court has personal jurisdiction over Millennium pursuant to the Tennessee long-arm statute, Tenn. Code Ann. § 20-2-214, because Millennium is registered to do business in Tennessee, has designated an agent for service of process located in Tennessee, has transacted business in Tennessee and otherwise purposefully availed itself of the privilege of doing business in Tennessee.

9. The causes of action that Aegis brings against Millennium substantially arise directly from Millennium's acts of unfair competition with Aegis with knowledge of Aegis's principal place of business in Nashville and regard the consequences and damage that Millennium intentionally caused Aegis in Tennessee and elsewhere.

10. The wrongful actions taken by Millennium that are detailed in this Complaint have a substantial connection to Tennessee, and the exercise of jurisdiction by a federal court in Tennessee over Millennium is reasonable and proper.

11. Pursuant to 28 U.S.C. § 1391, venue is proper in the United States District Court for the Middle District of Tennessee because a substantial part of the events or omissions giving rise to Aegis's claims for relief occurred in this judicial district and because Millennium is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

12. Aegis began providing drug testing services for pain management physicians and clinics in 2006 after physicians requested testing due to problems associated with “false negative” test results provided by other laboratories.

13. Aegis quickly determined that historical approaches to urine drug testing were inadequate for pain management and that substantial investment in research was required to develop a more sensitive, comprehensive, and accurate testing approach.

14. More specifically, historical urine drug testing programs have tested for relatively few drugs and drug classes, have used relatively high testing thresholds that assess only for high dose drug use, and have targeted only the few predominant urine metabolites providing evidence of such drug use.

15. Pain management physicians need compliance testing programs to answer two questions: (1) is the drug that the physician prescribed actually in the patient’s system (which can show both that the patient is complying with taking prescribed treatment and can rule out that the patient is selling controlled substances); (2) and is there some other drug in the patient’s system not prescribed by the physician (which can indicate either illicit drug use or doctor shopping by the patient in question and which may create harm to the patient or complicate patient therapy).

16. Aegis’s compliance testing for pain management physicians is designed to target more drugs and drug classes, to do so at lower threshold levels, and to detect less common urine metabolites.

17. Aegis’s compliance testing for pain management physicians is also designed and implemented in a manner that guards against and negates the ability of the drug abusing

population to use products or implement strategies to avoid detection of drug use by compliance testing.

18. Unlike many other laboratories operating in the marketplace, Aegis considers the use of point-of-care testing devices, including insta-cups, and bench top instruments or tabletop analyzers to be of very limited utility for pain management physicians.

19. Such point-of-care testing devices have limited drug detection capability, use very high testing thresholds, and suffer from inaccuracies involving both false negatives and false positives. Further, insta-cup point-of-care testing devices have not been designed or approved for use for the pain management application. Such testing devices have been primarily designed and applied for workplace drug testing and to a more limited extent emergency room testing for overdoses.

20. Because some of Aegis's pain management physician customers believe that the "instant result" that such point-of-care testing devices appear to provide can have a deterrent effect on drug-seeking patients who otherwise lack awareness of the limitations of such tests, Aegis does make insta-cups available to those pain management physicians who request them, but only upon very strict terms.

21. Specifically, Aegis requires physician customers who wish to be supplied such insta-cups to execute a contract prior to delivery of any such insta-cups.

22. Aegis's contract provides that the insta-cups are being provided only for the deterrent effect and for use in sending the sample to Aegis for comprehensive testing. The contract also specifically requires the physician customers to agree that they will not bill government or private payers for the point-of-care test that can be performed using the cup.

23. Defendant Millennium markets itself as a full-service clinical testing and urine drug screening operation and has publicly-communicated that most of the urine specimens that it tests are referred by physicians treating patients for chronic pain and pain management.

24. Aegis's employees and agents, and Millennium's employees and agents, are often competing for the same customers in Tennessee and in other states, including situations in which Millennium makes sales visits to physicians' offices or clinics in Tennessee and in other states where Aegis is already providing compliance testing services to such physicians or clinics.

25. Millennium markets and advertises the availability of close communications between its sales and service representatives and its physician customers.

26. Unlike Aegis, Millennium seeks to steer pain management physicians to the use of its services by touting a relationship with Millennium that combined with point-of-care testing devices can produce a lucrative, profit center for physician practices.

27. As part of Millennium's sales presentations and marketing efforts directed at physicians, Millennium asserts that physicians can earn tens or hundreds of thousands of dollars annually by participating in a panoply of unnecessary testing for corresponding billing schemes.

28. Millennium's sales representatives also present variations of these same kinds of marketing communications to customers through email and other media. An example of one such email sent by Millennium to an Aegis customer on October 28, 2010 is attached as **Exhibit 1**. As is reflected on **Exhibit 1**, Millennium's sales representative alleges to the physician that "[d]uring the 3-4 months you're out on maternity-leave your clinic will lose an estimated \$250,000 to \$400,000 in potential point-of-care reimbursements."

29. Among the various schemes and practices that Millennium has espoused to physician customers, including pain management physicians to whom Aegis is currently (or was

at the time of the communication) providing compliance testing services, in an effort to convince physicians to become customers of Millennium instead of Aegis are:

- the provision of staff to referring physicians at no cost to the physicians;
- access to free resources to assist physicians in enhancing revenues;
- supplying referring physicians urine testing cups that can be used by the physicians to bill for low level, initial diagnostic screening testing services;
- offering free, below market and/or improper “per click” (payment per unit of service) equipment lease arrangements for access to tabletop analyzers to perform additional point-of-care testing;
- instructing pain management physicians on billing and coding protocols abandoned by CMS in order to generate multiple billings;
- arranging for “pass-through” billing where, upon information and belief, the physician requests and directly purchases laboratory services provided by Millennium and sold by it at a reduced rate to the physician, the physician bills the patient and/or private insurers at a marked up rate for a profit and then sends the urine sample to Millennium for additional duplicative testing and billing; and
- developing a variation on “pass-through” billing where, upon information and belief, the physician purchases a fractional ownership share in a local Millennium affiliated screening laboratory, either directly bills patients for urine samples sent for screening at such laboratory and/or receives a portion of the local laboratories billings as a “dividend” or other “return on investment,” which is then followed by such samples being sent to Millennium for additional duplicative testing and billing.

30. Relationships between clinical laboratories and referring physicians are highly scrutinized by the Office of Inspector General (“OIG”) for the Department of Health and Human Services (“DHHS”) and the Centers for Medicare and Medicaid Services (“CMS”) because of the high risk of fraud and abuse inherent in such relationships. The statutes governing these relationships generally include the Anti-Kickback statute, 42 U.S.C. § 1320a-7b and the Stark law, 42 U.S.C. § 1395nn.

31. The Anti-Kickback statute makes it unlawful to pay, offer, receive or solicit remuneration as an inducement or reward for referrals of services payable by Medicare or Medicaid. 42 U.S.C. §1320a-7b(b). Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a federal health care program, the statute is violated. Remuneration includes any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. 42 C.F.R. § 411.351. The statute has been interpreted to cover any arrangement where even one purpose of remuneration was to obtain money for the referral of services or to induce further referrals.

32. The Stark law makes it unlawful for a physician to refer a Medicare or Medicaid patient for certain designated health services (“DHS”), such as clinical laboratory services, to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. *See generally* 42 U.S.C. § 1395nn. It also prohibits the entity furnishing DHS from submitting claims to Medicare, Medicaid, the beneficiary, or any other entity for DHS that are furnished as a result of a prohibited referral. For purposes of the Stark law, a financial relationship is a compensation arrangement or an ownership or investment interest in an entity. *See* 42 U.S.C. § 1395nn(a)(2). A compensation arrangement is any arrangement involving any remuneration between a physician (or an immediate family member of the physician) and an entity other than an arrangement involving only remuneration described in section 1877(h)(1)(C). 42 U.S.C. § 1395nn(h)(1). Subsection (C) defines remuneration to include “any remuneration, directly or indirectly, in cash or in kind.” *Id.*; 42 C.F.R. § 411.351. However, the Social Security Act also identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the physician self-referral prohibition. *See* CMS Advisory Op. No. CMS-AO-2010-01 at page 2

(June 2010). “Such remuneration includes the provision of items, devices, or supplies that are used solely to … collect, transport, process, or store specimens for the entity providing the item, device, or supply.” *Id.* at 2-3 (citing 42 C.F.R. § 411.351).

33. The OIG has specifically identified certain arrangements between clinical laboratories and health care providers that implicate the Anti-Kickback Statute. *OIG Special Fraud Alerts*, Department of Health and Human Services, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994).

Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business. The same is true whenever a referral source solicits or receives anything of value from the laboratory.

Id. Certain inducements offered by clinical laboratories may implicate the Anti-Kickback Statute such as the provision of equipment that may yield independent value to referring physicians when not “exclusively used for, performance of the outside laboratory’s work.” *Id.*

When one purpose of these arrangements is to induce the referral of program-reimbursed laboratory testing, [the OIG posits that] both the clinical laboratory and the health care provider may be liable under the statute and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Id. at 65377-78.

34. The OIG has also warned that the provision of laboratory personnel to a physician’s office can implicate the Anti-Kickback Statute.

While the mere placement of a laboratory employee in the physician’s office would not necessarily serve as an inducement prohibited by the Anti-Kickback statute, the statute is implicated when the [employee] performs additional tasks that are normally the responsibility of the physician’s office staff.

Id. at 65377. If the laboratory employee performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that the laboratory is providing a benefit in return for the physician's referrals. *Id.*

35. The provision of free "resources" to referring physicians reduces costs the physicians would otherwise be obligated to incur. The OIG has stated that the receipt of free services, the cost of which a provider would otherwise be obligated to incur, is a "tangible benefit" to the provider and raises an inference that the services are intended to influence the provider's choice of a laboratory. See OIG Advisory Opinion, No. 08-06 at page 5 (May 2008). This inference is further supported when a lab offers the services for the purpose of retaining or obtaining business. *Id.*

The OIG's position on the provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the Anti-Kickback statute, depending on the circumstances.

...
In particular, the OIG consistently has distinguished between a provider that offers free items and services that are integrally related to that provider's services, and those that are not.

...
When a party in a position to benefit from referrals provides free administrative services to an existing or potential referral source, there is a risk that at least one purpose of providing the services is to influence referrals.

OIG Advisory Opinion No. 10-20 at pages 4-5 (Sept. 2010); OIG Advisory Opinion No. 10-13 at page 4 (Aug. 2010); OIG Advisory Opinion No. 10-04 at page 4 (May 2010).

36. It is clear that the OIG takes a critical view of arrangements where clinical laboratories provide items and/or services to referring physicians which benefit such physicians in a way that is not absolutely integral to a laboratory's performance of its work. Millennium has participated in and continues to participate in these high risk activities specifically identified by the OIG.

37. First, Millennium markets and solicits business from referring physicians by offering personnel (services). It offers laboratory assistants to referring physicians to provide services separate and apart from tasks directly related to the collection and processing of the laboratory specimens Millennium uses for its testing. No payment is required for these supporting personnel. This arrangement of providing staff to perform additional tasks on behalf of the physician's office is precisely the kind of arrangement which the OIG concludes violates the Anti-Kickback Statute. *OIG Special Fraud Alerts*, Department of Health and Human Services, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994). There can be no other reason for these free services other than to induce or provide services in exchange for referrals. (A copy of a December 1, 2010 email from a Millennium sales representative to a potential customer specifically offering billing schemes and methods for the physician to "maximize profits" and offering laboratory assistants is attached as **Exhibit 2**.)

38. Millennium also offers its referring physicians a myriad of other additional free "resources" including: complimentary billing resources for coding and reimbursement support tools, and complimentary training and education to physicians and staff. These two "resources" have been identified by the OIG as indicators of unlawful activity in suspect incentive arrangements. *Id.* Millennium's provision of such tools that are used to enhance the physician's practice and revenue stream without cost to the physician is condemned by the OIG as an illegal kickback akin to the provision of free support staff or free equipment. *Id.* at 65376. (A copy of a November 28, 2010 email from Millennium to a potential customer touting a number of these resources is attached as **Exhibit 3**; see also attached **Exhibit 2**.)

39. In addition to the provision of free support staff and services, the Federal Government has taken an equally critical view of providing free items and equipment to referral

sources. Specifically, in the context of clinical laboratories, CMS has warned that such items or equipment that are not solely used to collect, transport, process or store specimens for lab testing billed by the laboratory can violate the Stark law. *See* CMS advisory opinion, CMS-AO-2010-01 (June 2010).

40. CMS considers arrangements involving clinical laboratories that furnish free equipment to referring physicians a compensation arrangement under the Stark law. *Id.* at 3. CMS goes further to explain that if free equipment is not used by the physicians solely to collect, transport, process or store specimens referred to the lab, the improper remuneration falls outside of any exception to the Stark law and is thus prohibited. *Id.*

41. Like CMS, the OIG has been critical of arrangements where the clinical laboratories furnish free items or equipment to referring physicians. Indeed, the provision of such items and equipment have, according to the OIG, “all the hallmarks of … disfavored arrangements” in a clinical lab setting. *See* OIG Advisory Opinion, No. 08-06 at page 5 (May 2008).

42. Millennium’s marketing techniques and relationships with referring physicians through the offering and provision of free services are in direct contradiction of the Stark and Anti-Kickback laws.

43. Similar to the provision of free services, Millennium solicits and markets to physicians sometimes free, and sometimes below market value, items and equipment in direct contradiction to guidance from the OIG and CMS. Millennium provides point-of-care testing devices, including insta-cups and desk top analyzers for use as part of illegal profit generating schemes as a way of retaining existing clients and enticing prospective physicians all in unfair and illegal competition with Aegis.

44. While the provision of free insta-cups alone is not unlawful, the context in which Millennium markets and provides such items creates independent value to referring physicians. Specifically, Millennium promotes and teaches physicians to use the insta-cups and then send them to Millennium for additional duplicative testing and billing. Moreover, as an attestation to the lack of utility to pain management physicians, the duplicative testing and billing is performed by Millennium irrespective of whether the insta-cup screen is negative or positive. (See **Exhibit 4**, Millennium Test Protocol - For Use With Point of Care Urine Test Devices). Thus, Millennium is providing to the physicians items at little or no cost, which are designed to “maximize profits” and enhance the physician’s revenue.

45. Additionally, Millennium promotes the physician’s use of analyzers provided through a purported independent third party entity - Alternate Biomedical Solutions (“ABS”) - on terms that are free and/or below market value, that sometimes impose no risk on the physicians through capital expenditure, and that fluctuate depending on the volume or value of referrals. Millennium markets these analyzers to physicians to be leased and used by the physicians to enhance the physician’s practice revenue. While some physicians are required to pay up to \$29,000 to purchase the instrument, these arrangements are sometimes offered by Millennium on a “per click” fee structure, allowing referring physicians the opportunity to receive a free instrument and only pay between \$8 and \$11.80 each time the analyzer is used, depending on the volume of patients tested each month. The analyzers in this scheme provide independent value to the physicians separate and apart from the purported purpose of assisting in the provision of laboratory testing. While leasing of equipment for testing purposes is not an inherently unlawful business structure, the related exception and safe-harbor under the Stark and Anti-Kickback statutes protecting such arrangements specifically prohibit the use of a “per click”

arrangement and prohibit the fees from being determined by volume or value of referrals. *See* 42 C.F.R. § 411.357(b); 42 C.F.R. § 1001.952(c). (Copies of cost per sample quotes provided by Millennium to potential physician customers, sample contract agreement documents, and related marketing materials, as well as another sample quote invoice for purchase of the same instrument to another physician customer are attached as Collective **Exhibit 5.**)

46. Just as it does for the insta-cups, Millennium also “teaches” physicians to bill for the screening test performed by the desktop analyzer, and then to send the urine sample to Millennium for additional duplicative testing and billing.

47. Millennium’s referring physicians receive, and prospective customers are offered, these below market, “per click” arrangements with ABS for the enhancement of the physician’s revenue stream. Millennium is marketing such services as an inducement to do business, or remuneration for continued business, with Millennium.

48. Through the provision of free insta-cups and free or below market rental of analyzers, Millennium willfully and improperly solicits business from referring physicians, many of whom are Aegis’ clients or prospective clients, by offering schemes through which such physician can “obtain money for the referral of services or to induce further referrals.” *See* OIG Advisory Opinion, No. 08-06 at page 5. For these reasons, Millennium is clearly operating outside the boundaries of federal and state law and creating an unfair field of competition.

49. In addition to the provision of free items and services discussed above, Millennium’s marketing strategies to solicit Aegis’ clients include misrepresentations of CMS coding guidelines. Specifically, as related to the billing of drug screens, both simple and complex, CMS recategorized CPT codes G0431 and G0434, which allow for the initial point-of-care testing in the physician’s office as well as complex drug testing in an outside clinical

laboratory. See CMS MLN Matters article No. MM7266 (Feb. 11, 2011) (**Exhibit 6**); CMS MLN Matters article No. SE1105 (**Exhibit 7**); CY 2011 CMS Clinical Laboratory Fee Schedule. Upon information and belief, Millennium has and continues to market and advertise billing protocols that undermine CMS guidance regarding the proper coding and reimbursement practices for clinical laboratories and referring physicians. Such efforts by Millennium include continuing to inform physician customers and potential customers that they can legally bill government and private insurance programs multiple units for single testing event devices by billing as many units as there are panels in each test kit. Through their blatant misrepresentations and the promotion of illegal coding and billing practices, including duplicative testing and billing practices, Millennium has created false and unlawful expectations for physician reimbursements. (See **Exhibit 3**.)

50. Millennium also engages in internal billing practices inconsistent with CMS and OIG guidance. One of the most common types of fraud involving the filing of false claims is “unbundling.” *Medicare Payments for Clinical Laboratory Services: Vulnerabilities and Controls*, statement of G. Grob, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, Dept. of Health & Human Services before the Expert Committee on Medicare Payment Methodology for Clinical Laboratory Services of the Institute of Medicine at 7, OEI-05-00-00070 (Jan. 20, 2000) (See **Exhibit 8**). “Unbundling occurs when a laboratory bills separately for some, or all tests, analyzed simultaneously by a single piece of equipment on a single patient specimen.” *Id.* at 7-8. In its 2011 Work Plan, the OIG outlined its intent to stop what was believed to be excessive laboratory billing caused by the unbundling of claims that are required to be billed together. *Laboratory Test Unbundling by Clinical Laboratories*, Office of Inspector General Work Plan FY 2011 at I-17 (2011) (See **Exhibit 9**); see also CMS Medicare

Claims Processing Manual, Pub. No. 100-04, ch. 16 § 90 (**Exhibit 10**); CMS National Correct Coding Initiative Policy Manual for Medicare Services, version 16.3 at xi-xiii (Oct. 1, 2010) (**Exhibit 11**).

51. Upon information and belief, Millennium engages in the act of segregating diagnostic tests ordered by physicians so that it may bill unbundled claims to maximize reimbursement. As part of this conduct, or in connection therewith, upon information and belief, Millennium has engaged in misrepresentation of the number of urine samples it has tested submitting forms indicating that tests being billed for were performed on different aliquots of urine specimens instead of on just one aliquot of a urine specimen. This illegal business practice results in unfair competition to other clinical laboratories like Aegis and is part of Millennium's false advertising in relation to its purported required specimen volume of "only 1ml-2ml of urine to test everything" and its purported "turn around time" as its advertised turn around time relates to fewer and less accurate laboratory tests.

52. Upon information and belief, Millennium also misrepresents the dates on which urine specimens were collected so that it may avoid denials of claims for payment. The misrepresentation of such "date of service" information is a violation of federal law.

53. Millennium's business practices are clearly designed to induce and/or reward pain management physicians for referrals of testing. Upon information and belief, Millennium also contracts with third parties who have existing relationships with physician practices to exploit those relationships to steer referrals to Millennium in exchange for payments. Such steering arrangements constitute an indirect payment, clearly prohibited by the plain language of the Anti-Kickback statute. 42 U.S.C. §1320a-7b(b).

54. Activities such as those described above create false expectations and misunderstandings by referring physicians who currently or may otherwise use Aegis for their compliance testing services or create an unlevel playing field in the marketplace disallowed by law in addition to the loss of business. Such improper activities require substantial financial investment on the part of Aegis to restore and maintain business relationships.

55. Upon information and belief, Millennium also engages in “pass through” billing arrangements with physician customers that result in deceptive and illegal billing practices and which constitute illegal fee divisions. In implementing such pass-through billing arrangements, the physician requests and directly purchases laboratory services provided by Millennium and sold by it at a reduced rate to the physician, the physician bills the patient and/or private insurers at a marked up rate for a profit and then sends the urine sample to Millennium for additional duplicative testing and billing.

56. Upon information and belief, Millennium has also developed a variation of “pass through” billing arrangements in which the physician purchases a fractional ownership share in a local Millennium affiliated screening laboratory, either directly bills patients for urine samples sent for screening at such laboratory and/or receives a portion of the local laboratories billings as a “dividend” or other “return on investment,” which is then followed by such samples being sent to Millennium for additional duplicative testing and billing.

57. The OIG sharply criticizes patient steering arrangements “structured so as to pose a heightened potential for [] unfair competition.” *See* OIG Advisory Op. No. 08-15 (Oct. 2008); OIG Advisory Op. No. 08-21 (Dec. 2008) Millennium’s “pass-through” billing arrangements, as discussed above, are a clear example of such steering arrangements whereby physicians are inappropriately incentivized to funnel all patient testing to a Millennium lab. Further, Tenn.

Code Ann. § 63-6-214 empowers the Board of Medicine to impose a number of different forms of disciplinary action against a physician, including but not limited to license revocation, for “unethical conduct” or for “fraud or deceit in the practice of medicine.” *See* Tenn. Code Ann. §§ 63-6-214(b)(1) and (3). In addition, Tennessee law prohibits physicians from dividing or agreeing “to divide any fee or compensation of any sort received or charged in the practice of medicine . . . with any person, without the knowledge and consent of the person paying the fee or compensation, or against whom the fee may be charged.” *See* Tenn. Code Ann. § 63-6-225(a).

COUNT I:
False Advertising in Violation of The Lanham Act, 15 U.S.C. § 1125(a)

58. Aegis hereby incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

59. Millennium’s advertising claims constitute false and misleading statements in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

60. Millennium continues to make false and misleading statements in commercial advertisements regarding the nature and utility of its services, the legality of its business practices and the billing practices that it advocates for use by its physician customers.

61. Millennium continues to make false and misleading statements in commercial advertisements claiming that “it tests every specimen that arrives at [its] lab for every drug and metabolite [it tests] for” but only bills insurance for the physician’s panel and that it “only needs 1mL-2mL to run” its tests in comparison to other labs needing “15mL-30mL to run just the drugs [the physician customer sets up on their] protocol.”

62. Millennium continues to make false and misleading statements in commercial advertisements claiming that physician customers who choose other laboratories over

Millennium are missing out on legal opportunities to increase their revenue from point-of-care reimbursements by tens of thousands of dollars each month.

63. These false and misleading advertising claims by Millennium are likely to deceive customers regarding the true features and characteristics of Millennium's drug testing services.

64. Further, these false and misleading advertising claims by Millennium are likely to deceive customers regarding whether use of Millennium's drug testing services and participation in the billing practices advocated by Millennium comply with the law.

65. Millennium's false and misleading advertising claims influence customer purchasing decisions.

66. Aegis has been and continues to be injured as a result of Millennium's false and misleading advertising claims.

67. Millennium's drug testing services are offered, advertised, and sold to customers throughout the country and, as a result, Millennium's false and misleading statements affect interstate commerce.

68. Millennium knew its advertising was false and misleading or acted with reckless disregard as to the truthfulness of its statements to customers.

69. As a direct and proximate result of Millennium's conduct in violation of the Lanham Act, Aegis has incurred actual damages and continues to incur actual damages, entitling Aegis to an injunction, corrective advertising, treble damages, as well as disgorgement by Millennium of the profits it has derived from its unlawful acts and the increase of such an award pursuant to equitable principles and in accordance with 15 U.S.C. §§ 1116 and 1117.

COUNT II:
Intentional Interference with Existing or Prospective Business Relationships

70. Aegis hereby incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

71. Business relationships exist between Aegis and numerous pain management physicians and clinics. Specifically, these physicians and clinics use Aegis to provide compliance testing services involving analysis of urine and/or oral fluid for the presence of illegal or prescription drugs and drug metabolites in patient samples.

72. Upon information and belief, Millennium knew of the business relationships in existence between Aegis and the pain management physicians and clinics to which Aegis provides compliance testing services, and Millennium, with knowledge of such relationships, engaged in the described illegal activities and made false and misleading statements regarding the legality of Millennium's billing practices and business arrangements with the intent of interfering with and/or causing such pain management physicians and clinics to terminate their business relationships with Aegis.

73. As described above, Millennium's means of influencing pain management physicians and clinics were improper and driven by an improper motive.

74. Aegis has suffered injuries to its relationships with its customers and prospective customers as a result of Millennium's acts of tortious interference and has been forced to, and, if Millennium's actions are not enjoined, will likely continue to be forced to, incur significant costs and expenses explaining to its customers why Millennium's proposed billing practices and business arrangements are illegal.

COUNT III:
Common Law Unfair Competition

75. Aegis hereby incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

76. Millennium's illegal actions described above constitute unfair competition and have damaged Aegis.

77. By soliciting Aegis's customers through proposals involving billing methods and business practices in violation of federal and state law, Millennium improperly interfered with Aegis's business prospects in a manner that constitutes unfair competition.

78. Millennium's unfair competition has impaired Aegis's ability to compete in the market for the provision of compliance testing services to pain management physicians and clinics, has caused Aegis to lose customers, and has forced Aegis to expend significant resources educating its customers regarding the illegality of, and risk associated with, the billing methods and business practices being proposed and marketed by Millennium.

COUNT IV:
Unfair or Deceptive Practices in Violation of
the Tennessee Consumer Protection Act (Tenn. Code. Ann. §§ 47-18-101 et seq.)

79. Aegis incorporates the allegations contained in the above paragraphs as if fully set forth herein.

80. The above-alleged conduct and business practices of Millennium constitute acts and practices which are deceptive in violation of Section 104(b) of the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-104(b)(5), (7), (11), (12), and (27).

81. Aegis is entitled to recover the relief and damages specified in Tenn. Code Ann. §§ 47-18-108 and 47-18-109 from Millennium as a result of its violation of Section 104(b) of the Tennessee Consumer Protection Act.

COUNT V:
Declaratory Judgment

82. Aegis hereby incorporates by reference the allegations in the above paragraphs as if fully set forth herein.

83. An actual controversy exists regarding whether the billing practices and other business arrangements pursued with pain management physicians by Millennium violate federal law, state law, or both. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* and Federal Rule of Civil Procedure 57, Aegis is entitled to a judgment declaring that Millennium's billing practices and other business arrangements pursued with pain management physicians violate the federal Anti-Kickback statute (42 U.S.C. § 1320a-7b), the Stark Law (42 U.S.C. § 1395nn), and/or are in direct contravention of related federal regulations including 42 C.F.R. § 411.357(b); 42 C.F.R. § 1001.952(c), and that participation with Millennium in such activities subjects its customers to potential liability under Tenn. Code Ann. § 63-6-214(b)(1), (b)(3) and/or Tenn. Code Ann. § 63-6-225 and further declaring that Millennium is prohibited from continuing to engage in conduct in violation of those provisions of federal and state law.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiff Aegis Sciences Corporation respectfully prays that the Court grant the following relief:

A. That process be issued and that Millennium be made to appear and answer this Complaint and the allegations against it;

B. A judgment that Millennium has engaged in false advertising, promotion, and descriptions in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), that Millennium has intentionally interfered with Aegis's existing or prospective business

relationships, that Millennium has engaged in unfair competition with Aegis, and that Millennium has violated the Tennessee Consumer Protection Act;

C. A judgment, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, declaring that Millennium's billing practices and business arrangements with pain management physicians described herein violate the federal Anti-Kickback statute (42 U.S.C. § 1320a-7b), the Stark Law (42 U.S.C. § 1395nn), and/or are in direct contravention of related federal regulations including 42 C.F.R. § 411.357(b); 42 C.F.R. § 1001.952(c), and that participation with Millennium in such activities subjects its customers to potential liability under Tenn. Code Ann. § 63-6-214(b)(1), (b)(3) and/or Tenn. Code Ann. § 63-6-225 and further declaring that Millennium is prohibited from continuing to engage in conduct in violation of those provisions;

D. A permanent injunction enjoining Millennium and its officers, directors, agents, servants, employees, and all persons in active concert and participation with it, from false advertising, promotion, and descriptions in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) applicable state statutory law and common law; and continuing to engage in its illegal acts of intentional interference with Aegis existing and prospective business relationships, unfair competition and in violation of the Tennessee Consumer Protection Act;

E. A permanent injunction requiring Millennium and its officers, directors, agents, servants, and employees to engage in corrective advertising to address its prior false, misleading, and deceptive advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);

F. In accordance with the Lanham Act, applicable Tennessee statutory law and common law, as well as the statutory law and common law of any additional statutes deemed applicable under a choice of law analysis and determination, an award to Aegis of its damages,

treble damages, Millennium's profits derived from its unlawful acts increased pursuant to principals of equity, and an award of damages for corrective advertising;

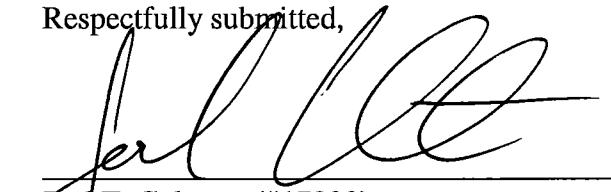
G. An award to Aegis of its attorneys' fees and costs; and

H. An award to Aegis of such other and further relief, in law and equity, as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Aegis demands a jury trial on all claims for which it is entitled to a trial by jury.

Respectfully submitted,



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